

## **REMARKS**

In this paper, claims 1, 4 and 20-27 are amended, claims 3 and 7-17 canceled and new claims 28 and 29 are added. Claims 1, 4-5, and 18-29 are pending. Reconsideration of this application, as amended, is requested.

### **Species Election**

Applicants confirm the election of Species A, drawn to Figure 2. Claims 7-17, falling under Species B, have been canceled herein without prejudice, for prosecution in a divisional application.

### **Double Patenting**

Claims 1, 3-5 and 18-27 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over various claims of U.S. Patent No. 6,618,934.

Although Applicants do not necessarily agree with the properness of this rejection, Applicants will submit a Terminal Disclaimer, if the scope of the claims remains the same, upon indication that the claims are otherwise in condition for allowance.

### **103 Rejections**

Claims 1, 3, 18, 19 and 21-27 were rejected under 35 U.S.C. 103(a) as unpatentable over U.S. Patent No. 5,708,247 to McAleer et al. in view of U.S. Patent No. 5,387,329 to Foos et al. Claim 4-5 and 20 were rejected based on McAleer et al. and Foo et al., further in view of U.S. Patent No. 6,129,823 to Hughes et al. Applicants disagree.

Claim 1 has been amended to clarify the steps in making the electrochemical sensor. Claim 1 recites that a plurality of working electrodes and a plurality of counter electrodes are applied on a substrate (such as by printing, claims 18 and 19), and that the electrodes are overlaid with a spacer layer and then a second substrate. A sample chamber is created that has a volume of no more than 1  $\mu\text{L}$  (or no more than about 0.5  $\mu\text{L}$  or about 0.25  $\mu\text{L}$ , claims 23 and 29). A portion of the spacer layer can be removed to form the sample chamber (claims 21, 22). From the multi-layer stack, a plurality of electrochemical sensors are separated, so that each

electrochemical sensor has at least one working electrode, at least one counter electrode, and at least one sample chamber region, and where the two substrates have generally the same length and width. Claim 24 is similar, but includes applying a plurality of indicator electrodes.

McAleer et al. provides a disposable glucose test strip that has a working electrode (14, 14') and a reference/counter electrode (15, 16) on a substrate (10). A first working layer (17) and a second working layer (71; FIG. 7) are provided over a portion of the electrodes and a portion of the electrodes are covered with a non-conductive or insulating mask (18). A region of the working coating (17) is present over the insulating mask 18 to make contact with the conductive electrode (16); col. 3, lines 36-38.

McAleer et al. does not provide a second substrate, that in the resulting sensor strip, has generally the same length and width as the substrate on which the electrodes are present. McAleer et al. merely provides a small top cover (23) to prevent splashing of the blood sample. This top cover does not generally mirror the shape and size of the substrate, but merely provides a little 'patch' over the sample chamber and electrode area; see FIG. 2 of McAleer et al.

McAleer et al. does not disclosing forming indicator electrodes nor a sample chamber volume of no more than 1 microliter.

The Office Action turns to Foo et al. for the teaching of a sample chamber volume of less than 1 microliter. Foo et al. discloses having a sample chamber volume of 0.8 to 3 microliters. Foo et al. does not, however, disclose or suggest having a sample chamber volume of no more than about 0.5  $\mu\text{L}$  (claims 23 and 29) or no more than about 0.25  $\mu\text{L}$  (claims 27 and 28). It would not have been obvious to one skilled in the art to make such small volume sample chambers, based on a teaching that is up to, and more than, 10 times the volume of what is claimed.

The Office Action also turns to Foo et al. for the teaching of indicator electrodes. Applicants disagree that Foo et al. provides indicator electrodes. An indicator electrode is used to determine when the measurement zone or sample chamber has been filled; see for example, page 4, lines 7-9 of the pending application. There is no structure in Foo et al. that provides such a feature. The Office Action cites "electrodes (50)", however, these are not indicator electrodes, as used in the pending application, but are merely reference electrodes, used to obtain a reading

in conjunction with the working electrodes 34. Foo et al. lacks the teaching of indicator electrodes. There is no teaching or suggestion in Foo et al., nor in McAleer et al. combined with Foo et al., of including indicator electrodes in the sensor strip.

Foo et al. also lacks a second substrate that has generally the same length and width as the substrate on which the electrodes are present. Foo et al. merely provides a small oval shaped cover member (64) to form the sample chamber (62). This cover member does not generally mirror the shape and size of the substrate, but merely provides an oval area used to define the sample chamber over the electrode area; see FIG. 5 of Foo et al. There is no teaching or suggestion in Foo et al., nor in McAleer et al. combined with Foo et al., of having a second substrate overlying the first substrate, that is generally the same length and width.

Regarding the addition of Hughes et al. to McAleer et al. and Foo et al., this combination is still lacking various recited details, such as the sample chamber volume, indicator electrodes, and that the second substrate has generally the same length and width as the substrate on which the electrodes are present.

At least for these reasons, Applicants contend that neither McAleer et al., Foo et al., Hughes et al., nor their combination, render unpatentable the pending claims, as amended. Withdrawal of these rejections is requested.

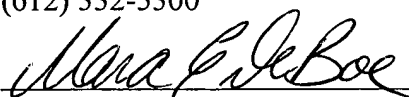
#### Summary

In view of the above amendments and remarks, Applicant respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

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